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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/550.115	04/14/2000	Ken-ichi Arai	084335/0120	8438

23533 7590 10/22/2002

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EXAMINER

MAYES, LAURIE A

ART UNIT PAPER NUMBER

1653

DATE MAILED: 10/22/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/550,115

Applicant(s)

ARAI ET AL.

Examiner

Laurie Mayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 November 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-14 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

The applicant's election of Group I is noted. However, upon careful review of the application, the restriction mailed on October 1, 2001 is withdrawn. Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 9, 11 and 13, drawn to a polypeptide having calcineurin-binding activity and to methods of administering the polypeptide, classified in class 514, subclass 2.
- II. Claims 2-5 and 14, drawn to DNA encoding a polypeptide having CN binding activity and a method of obtaining the polypeptide by recombinant means, classified in class 436, subclass 69.1.
- III. Claim 6, drawn to a method for screening a compound that inhibits the interaction between calcineurin and NF-AT, classified in class 435, subclass 7.1.
- IV. Claims 7, 8, 10 and 12, drawn to a compound isolable by the screening method, a pharmaceutical composition containing the same and a method of administering the compound, classified in class 514, subclass 2.

Claim 1 of Invention I encompasses 2 distinct proteins with different primary structure. The proteins are structurally different; therefore, the applicant must elect a specific sequence for examination. If Invention I is elected, claim 1 will be examined only in-so-far as it pertains to the elected SEQ ID NO.

Claim 2 encompasses DNAs encoding 2 different proteins. The applicant must select a specific sequence for examination. Applicant is advised that a reply to this requirement must include an identification of the peptide or nucleic acid that is elected consonant with this requirement, and a listing of all claims readable thereon, including and claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

This election requirement is not to be construed as a species election, as these compounds do not share a common primary structure and appear to be patentably distinct.

Should applicant traverse on the ground that these different compounds are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of Invention II are related to the protein of Invention I by virtue of encoding the same. The DNA molecule has utility for the recombinant synthesis of the host cell's protein. Although the DNA molecule and protein are related since the DNA encode the specific protein, they are distinct inventions because the protein product can be made by another and materially different process, namely, by synthetic peptide synthesis or purification from a natural source. Further, the DNA may be used for processes other than production of the protein, namely, nucleic acid hybridization assay.

Inventions I and III are related as a protein and a process of use. The protein is used as claimed in a pharmaceutical method.

Inventions I and IV are unrelated as they have different primary structures and intended uses.

Inventions II and III and II and IV are unrelated nucleic acids not used in the claimed screening process nor is there any physical relation to the structure of the antagonist.

Inventions III and IV are related as process of obtaining a compound and the compound itself. In the instant case the inventions are distinct because the in addition to screening to obtain the compound, the compound could be obtained by recombinant DNA methods.

Because these inventions are distinct for the reasons given above and have acquired a separate statuses in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached from Monday through Friday from 7 AM to 3:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 305-2923. The fax phone numbers for the

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organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

L. Mayes

Laurie Mayes
Patent Examiner
Art Unit 1653
October 21, 2002

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1000